

FORM PTO 1449 (modified)

Atty. Docket No.
K12383N

Serial No.
09/928198

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

Applicants
James A. Hoffmann, Jirong Lu

Filing Date
8/10/2001

Group
1647

3017 U.S. PTO
09/928198

08/10/01

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Sub-class	Filing Date If Appropriate
RMD	AA	5,162,306	11/10/92	Donaldson	514	12	—
	AB	5,508,261	04/16/96	Moyle, et al.	514	8	—
	AC	4,670,419	06/02/87	Uda, et al.	514	16	—
	AD	5,929,028	07/27/99	Skrabanja, et al.	514	2	—
	AE	5,733,572	03/31/98	Unger, et al.	424	450	—
	AF	5,650,390	07/22/97	Samaritani, et al.	514	8	—
	AG	5,087,615	02/11/92	Chappel	514	21	—
	AH	5,767,067	06/16/98	Arpaia, et al.	514	8	—
	AI	5,639,640	06/17/97	Reddy, et al.	435	325	—
RMD	AJ	5,889,110	03/30/99	Hutchinson	525	54.1	—

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Sub-class	Translation
							yes no
RMD	BA	1,340,132	11/17/98	Canada	—	—	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

RMD	CA	Voortman G, van de Post J, Schoemaker RC, van Gerven J M A., "Bioequivalence of subcutaneous injections of recombinant human follicle stimulating hormone (Puregon) by Pen-injector and syringe", Human Reproduction, Vol. 14, No. 7, pp. 1698-1702, 1999
RMD	CB	Reichert, Jr. LE, Ramsey RB, "Dissociation of Human Follicle-stimulating Hormone", The Journal of Biological Chemistry, Vol. 250, No. 8, pp. 3034-3040, April 25, 1975
RMD	CC	Shome B, Parlow AF, Liu W-K, Nahm HS, Wen T, Ward DN, "A Reevaluation of the Amino Acid Sequence of Human Follicitropin β -Subunit", Journal of Protein Chemistry, Vol. 7, No. 4, pp. 325-339, 1988

EXAMINER
Regina M. Koberg

DATE CONSIDERED
2/26/02

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

FORM PTO 1449 (modified)		Atty. Docket No. X12383N	Serial No. 091928198
INFORMATION DISCLOSURE CITATION IN AN APPLICATION		Applicant James A. Hoffmann, Jirong Lu	
		Filing Date 8/10/2001	Group 1647
RM	CD	Livesey JH, Roud HK, Metcalf ME, Donald RA, "glycerol prevents loss of immunoreactive follicle-stimulating hormone and luteinizing hormone from frozen urine", Journal of Endocrinology, Vol. 98, pp. 381-384, 1983	
	CE	Harvey SC, "Antiseptics and Disinfectants; Fungicides; Ectoparasiticides", The Pharmacological Basis of Therapeutics, 6 th Edition, 964-987, 1980	
	CF	Kesner JS, Knecht EA, Krieg, Jr. EF, "Stability of Urinary Female Reproductive Hormones Stored Under Various Conditions", Reproductive Toxicology, Vol. 9, No. 3, pp. 239-244, 1995	
	CG	Bontempo JA, "Chapter 5: Formulation Development", Development of Biopharmaceutical Parenteral Dosage Forms, pp. 109-142, 1997, published by Marcel Dekker, Inc.	
	CH	Rose MP, Gaines-Das RE, "Characterisation, calibration and comparison by international collaborative study of international standards for the calibration of therapeutic preparations of FSH", Journal of Endocrinology, Vol. 158, pp. 97-114, 1998	
	CI	"The United States Pharmacopeia, Twenty-First Revision", United States Pharmacopeial Convention, Inc., Official from January 1, 1985, Prepared by the Committee of Revision and published by the Board of Trustees, pp. 1491-1493, 1984	
	CJ	Wallhauser K-H, "Antimicrobial Preservatives in Europe: Experience with Preservatives Used in Pharmaceuticals and Cosmetics", with International Symposium on Preservation in Biological Products, San Francisco 1973, Develop. Biol. Standard, Vol. 24, pp. 9-28, 1974	
	CK	Akers MJ, "Considerations in selecting antimicrobial preservative agents for parenteral product development", Pharmaceutical Technology, May, 1984, pp. 36-46.	
	CL	Gonal-F [®] , (follitropin alfa for injection), for subcutaneous injection, Physicians' Desk Reference, 53 rd Edition, 1999, pp. 2991-2995, published by Medical Economics Company, Inc.	
	CM	Follistim [®] (follitropin beta for injection), Physicians' Desk Reference, 53 rd Edition, 1999, pp. 2128-2132, published by Medical Economics Company, Inc.	
	CN	Fertinex [®] (urofolitropin for injection, purified) for subcutaneous injection, Physicians' Desk Reference, 53 rd Edition, 1999, pp. 2988-2989, published by Medical Economics Company, Inc.	
	CO	Saxena BB, Rathnam P, "Amino Acid Sequence of the β Subunit of Follicle-stimulating Hormone from Human Pituitary Glands", The Journal of Biological Chemistry, Vol. 251, No. 4, pp. 993-1005, Feb. 25, 1976	
	CP	Shome B, Parlow AF, "Human Follicle-Stimulating Hormone: First Proposal for the Amino Acid Sequence of the Hormone-Specific, β Subunit" (hFSH β), J. Clin. Endocrinol. Metab., Vol. 39, 187, pp. 203-205, 1974	
	CQ	Watkins PC, Eddy R, Beck AK, Vellucci V, Leverone B, Tanzi RE, Gusella JF, Shows TB, "DNA Sequence and Regional Assignment of the Human Follicle-Stimulating Hormone β -Subunit Gene to the Short Arm of Human Chromosome 11", DNA, Vol. 6, No. 3, pp. 205-212, 1987	
	CR	Guzman K, Mill K, CD, Phillips CL, Miller WL, "The Gene Encoding Ovine Follicle-Stimulating Hormone β : Isolation, Characterization, and Comparison to a Related Ovine Genomic Sequence", DNA and Cell Biology, Vol. 10, No. 8, pp. 593-601, 1991	
	CS	Maurer RA, Beck A, "Isolation and Nucleotide Sequence Analysis of a Cloned cDNA Encoding the β -Subunit of Bovine Follicle-Stimulating Hormone", DNA, Vol. 5, No. 5, pp. 363-369, 1986	
	CT	Hrai T, Takikawa H, Kato Y, "The gene for the β subunit of porcine FSH: absence of consensus oestrogen-responsive element and presence of retroposons", Journal of Molecular Endocrinology, Vol. 5, pp. 147-158, 1990	
	CU	Combarrous Y, "Molecular Basis of the Specificity of Binding of Glycoprotein Hormones to Their Receptors", Endocrine Reviews, Vol. 13, No. 4, pp. 610-691	
EXAMINER		DATE CONSIDERED 2/26/02	
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.			

[illegible]